K000905 Page 1 of 2

MAY 12 2000

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: March 17, 2000
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Optical Urethrotome	Model number: 8667.xxx, 8670.xxx, and others
Common name: Urethrotome	**Classification Name:** Urethrotome

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1	1 Optical Urethrotome 8664 / 8667	1 Richard Wolf
2	2 Optical Urethrotome 27068 / 27145	2 Karl Storz
3	3 Optical Urethrotome A3551-60, A3744-5	3 Olympus
4	4 Visual Urethrotome EVUS-22, G322	4 Circon-ACMI

1.0 Description

The optical urethrotomes are metal instruments equipped with blades, in various shapes, that can be elevated from their sheaths. They incorporate an optical channel for visual control.

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2.0 Intended Use

The optical urethrotomes with the appropriate stricture scalpels are used for the cold slitting of urethral stenosis (transurethrally) and stenosis of ureter at the kidney exit (precutaneously) under endoscopic control.

3.0 Technological Characteristics

The design of the submitted urethrotomes has been revised. Titanium is used to reduce the weight.

The scalpel blades, made of ceramic, provide improved sharpness life.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to devices sold by Richard Wolf, Karl Storz, Olympus, and Circon-ACMI.

5.0 Performance Data

The submitted devices are in conformance with the relevant provisions of the Medical Device Directive 93/42/EEC..

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa Date: Mar 17, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical
Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K000905
Optical Urethrotome
Dated: March 17, 2000
Received: March 21, 2000
Regulatory Class: II
21 CFR §876.4770/Procode: 78 EZO

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K000905

Device Name: Optical Urethrotomes

Intended Use:

The optical urethrotomes with the appropriate stricture scalpels are used for the cold slitting of urethral stenosis (transurethrally) and stenosis of ureter at the kidney exit (percutaneously) under endoscopic control.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000905